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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,200	09/18/2003	Kerstin Kuhn-Wache	PBD-00027	7181

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,200	KUHN-WACHE ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 26-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 26-31 and 41-45, are drawn to method of treatment for metabolic disease, classified in class 514, subclass 2.

II. Claims 32-40, drawn to pharmaceutical composition, classified in class 424, subclass 1.69.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case group I inventions are drawn to a method of treatment of metabolic diseases and group II inventions are drawn to pharmaceutical compositions. Diabetes mellitus being a metabolic disease; is treated by administering insulin. The metabolic disease such as diabetes does not have to be treated by administering a compound capable of binding to a secondary binding site of DPIV and DPIV like enzymes combined with an anti-diabetic agent as recited by applicants.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. The search for the each of the two groups of inventions is not co-extensive and hence a reference that would anticipate the invention of one group would not necessarily anticipate or

even make obvious another group. Hence restriction is proper, and not restrict would be an undue burden on the Examiner.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claim 27 and 33 are generic to a plurality of disclosed patentably distinct species of anti-diabetic agents such as DP IV inhibitors; PPAR agonists; biguanides, e.g. metformin, phenformin or buformin; protein tyrosine phosphatase-lB (PTP-IB) inhibitors; insulin and insulin mimetics; sulfonylureas and other insulin secretagogues; α-glucosidase inhibitors or acarbose; glucagon receptor agonists; GLP-I , GLP-I mimetics, and GLP-I receptor agonists; GLP-Z, GLP-2 mimetics, and GLP-2 receptor agonists or teduglutide; exendin-4, exendin-4 mimetics, exenatide; GIP, GIP mimetics, and GIP receptor agonists; PACAP, PACAP mimetics, and PACAP receptor 3 agonists; PYY, PYY mimetics, PYY receptor agonists, and PYY receptor antagonists; PPARδ agonists, anti-obesity compounds, an ileal bile acid transporter inhibitor, and anti-inflammatory agents.

The claims 27 and 33 also contains several cholesterol lowering agents such as,

- HMG-COA reductase inhibitors,
- sequestrants,
- nicotinyl alkohol, nicotinic acid and salts thereof,
- PPARα agonists,
- PPARγ agonists,
- PPARα/γ dual agonists,
- inhibitors of cholesterol absorption,
- acyl CoA:cholesterol acyltransferase inhibitors, and
- antioxidants,

listed under anti-diabetic agents. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of anti-diabetic agent for prosecution on the merits to which the claims shall be

restricted if no generic claim is finally held to be allowable. If the anti-diabetic agent selected is the aforementioned cholesterol reducing agent, then the applicant should pick one species among several listed for prosecution on the merit, even though this requirement is traversed.

Claims 28 and 34 contains several compounds such as GRF-peptide family, TFTSDY (SEO ID NO:1), TFTDDY (SEO ID NO:4), H-Ser-D- Glu-Thr-G1y-D-Val-D-Lys-D-Va1-OH, and compounds of formulas a) to d) (not shown here). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, even though this requirement is traversed.

Claim 30 lists several metabolic diseases such as, Syndrome X, impaired glucose tolerance, glucosuria, lipid disorders, dyslipidemia, hyperlipidemia, hypertriglyceridemia, hypercholesterolemia, low HDL levels, high LDL levels, metabolic acidosis, hyperglycemia, diabetes mellitus, diabetic neuropathy and nephropathy and of sequelae caused by diabetes mellitus in mammals, metabolism- related hypertension and cardiovascular sequelae caused by hypertension in mammals. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species metabolic disease listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, even though this requirement is traversed.

Claim 31 lists several non-metabolic disease conditions such as, prophylaxis and/or treatment of skin diseases, diseases of the mucosa, autoimmune diseases, inflammatory conditions, psychosomatic, neuropsychiatric and depressive illnesses, such as anxiety, depression, sleep disorders, chronic fatigue, schizophrenia, epilepsy, nutritional disorders, spasm

and chronic pain, atherosclerosis and its sequelae, vascular restenosis, irritable bowel syndrome, inflammatory bowel disease, including Crohn's disease and ulcerative colitis, other inflammatory conditions, pancreatitis, abdominal obesity, neurodegenerative disease, retinopathy, nephropathy, ovarian hyperandrogenism (polycystic ovarian syndrome), growth hormone deficiency, neutropenia, tumor metastasis, benign prostatic hypertrophy, gingivitis, osteoporosis, and other conditions. If applicants choose a treatment method for non-metabolic disease condition, they are required to select a single species from the above list of diseases for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, even though this requirement is traversed.

Currently, claims 26-34 and 37-45 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1 .143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

srg

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